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Supreme Court, U.S.
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No. 95-1010

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

EUGENE DUVALL; PATRICIA SUE DUVALL,
Petitioners,

v.

BRISTOL-MYERS SQUIBB, a Delaware Corporation;
MEDICAL ENGINEERING CORPORATION, a/k/a
SURGITEK/MEDICAL ENGINEERING CORPORATION,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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RESPONSE TO PETITION FOR WRIT OF CERTIORARI

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8 pp

QUESTION PRESENTED

Which state-law product liability claims are preempted by the Medical Device Amendments of 1976 to the Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*?

LIST OF PARENT COMPANIES AND NONWHOLLY OWNED SUBSIDIARIES

As required by Rule 29.6, the nonwholly owned subsidiaries of respondent Bristol-Myers Squibb Company are as follows:

Bristol-Myers Lion Ltd.; Bristol-Myers S.A.; Bristol-Myers Squibb G.M.B.H.; Bristol-Myers Squibb Korea Limited; Mead Johnson (Guangzhou) Ltd.; Instituto Bio-Medico S.A. de C. V.; Laboratories UPSA SAS; Nyagen; P. T. Squibb Indonesia; RCS Realty Corporation; Servicios Bio-Medicos de Compresion S.A.; Sino American Shanghai Squibb Pharma Ltd.; SMI Bristol Limited; Squibb of Bangladesh Limited; Squibb Nigeria Limited; Synbiotics Limited; UPSA Investissements; 2309 Realty Corporation.

Respondent Medical Engineering Corporation is a wholly owned subsidiary of respondent Bristol-Myers Squibb Company.

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STATEMENT OF THE CASE

Respondents adopt as their statement of the case the factual recitation set forth in Parts I and II of the opinion of the Court of Appeals for the Fourth Circuit in this matter, Pet. App. at 3-6.

ADDITIONAL REASONS FOR GRANTING THE WRIT

The question presented warrants this Court's plenary review. There is a significant conflict among the federal courts of appeals concerning the extent to which the Medical Device Amendments ("MDA") preempt state-law product liability claims. In the decision below, the Court of Appeals for the Fourth Circuit analyzed the preemption

issue in the context of petitioners' multiple claims, all premised on allegations that petitioner Eugene Duvall suffered injuries following the surgical implantation of a penile prosthesis manufactured and distributed by respondent Medical Engineering Corporation. The Court held that the MDA preempted petitioners' claims for breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, strict liability for defective design, strict liability for defective manufacture, strict liability for failure to warn, and negligence in the design, testing, manufacture, marketing, promotion and sale of the device. Based on this Court's decision in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 525-27 (1992) (plurality opinion), however, the Court held that express warranty claims were not preempted to the extent those claims were based upon respondent's "voluntary" promises. The Court expressly acknowledged that certain aspects of its holding were in conflict with decisions reached by other federal courts.

On January 22, 1996, this Court granted both a petition for writ of certiorari and a conditional cross-petition in the matter styled *Medtronic, Inc.* v. *Lohr*, Nos. 95-754 and 95-886. In *Lohr*, the Court of Appeals for the Eleventh Circuit held that the MDA preempted product liability claims alleging injuries caused by a defective cardiac pacemaker lead, to the extent those claims were premised on theories of negligent manufacture, negligent failure to warn, or strict liability for defective manufacture or labeling of the device. However, that Court held that the plaintiffs' claims were not preempted to the extent they were premised on allegations of negligent design or strict liability in tort based on a design defect.

The Court should review this case concurrently with *Lohr* for three reasons. First, because the state-law tort claims presented by the plaintiffs in *Duvall* are different from, and broader than, the claims presented by the plaintiffs in *Lohr*, a decision by this Court in *Lohr* alone would not determine the full scope of state-law preemp-

tion under the MDA, particularly with respect to implied and express warranty claims available under the Uniform Commercial Code. This distinction is significant because there is a substantial conflict among the circuits over how this Court's decision in *Cipollone* guides the analysis of the MDA's preemptive effect on warranty claims. *See, e.g.*, Pet. App. at 15-16 (noting conflict). This Court's eventual decision in *Lohr* may not address that conflict.

In stark contrast to the approach adopted by the Courts of Appeals in *Lohr* and *Duvall*, as well as other federal courts in dozens of published decisions—all of which hold that the MDA preempts at least some state-law claims—the Court of Appeals for the Ninth Circuit recently held that the MDA does not preempt *any* state-law product liability claims. *See Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir.), *amended*, 1995 W.L. 694923 (9th Cir. 1995). Respondents believe that the Court of Appeals' decision in this case is essentially correct in its approach to the preemption issues posed by the MDA and further agree that, under the statute, preemption must be determined in light of the particular claims made by a plaintiff. The most appropriate vehicle for this Court to decide this imprortant question of federal law is a case like this one, in which the plaintiffs raised, and the court below resolved, the full array of typical state-law product liability claims.

Second, respondents believe that this Court may be aided in its analysis of the preemptive effect of the MDA, and particularly the 510(k) notification procedure set forth at 21 U.S.C. § 360(k) and 21 C.F.R. § 807.81, by its plenary consideration of this case. The Court of Appeals in this case, unlike in *Lohr*, based its preemption analysis in large measure on the specific requirements imposed by the 510(k) notification procedure applicable to respondents' penile implant as reflected in the record created in the district court. *See* Pet. App. at 5-6, 14-15, 17-18. It does not appear that either the district court or the Court of Appeals in *Lohr* performed (or was

able to perform based on the record presented), a similar analysis of the procedures and specific requirements followed by Medtronic during the FDA's 510(k) review of that company's device.

Third, the penile implant at issue in this case underwent a product "investigation" pursuant to the FDA's investigational device exemption ("IDE") procedures, 21 U.S.C. § 360j(g), a separate component of the regulatory scheme set forth by Congress and implemented by the FDA. *See* Pet. App. at 5-6. The investigation of respondents' device included clinical trials conducted in accordance with an Investigational Plan and research protocols approved by the FDA. *See* 21 C.F.R. § 812.1 *et seq*. The results of the clinical trials were then presented to the FDA during the 510(k) review process to demonstrate the safety and efficacy of respondents' device. By contrast, the pacemaker lead in *Lohr* did not receive an IDE, and therefore was not subjected to clinical trials pursuant to an Investigational Plan approved by FDA, prior to receiving approval from the FDA to market the device. Given that the MDA expressly preempts any state-law safety or effectiveness requirement "which is different from, or in addition to, *any requirement applicable under this chapter* to the device," 21 U.S.C. § 360k(a) (emphasis added), this distinction may be an important factor in the Court's interpretation of the scope of federal preemption under the statute.

For these reasons, respondents suggest that this Court grant the Petition for Writ of Certiorari in this case and order that briefing on the merits and argument in this case be conducted in tandem with the schedule adopted by the Court in *Lohr*. If the Court directs, respondents' counsel will be prepared to abide by the *Lohr* schedule, calling for the filing of petitioners' brief on the merits on March 1, 1996, and respondents' brief on the merits on March 29, 1996.

CONCLUSION

For the reasons stated, respondents Bristol-Myers Squibb Company and Medical Engineering Corporation respectfully request that the Petition for Writ of Certiorari be granted, and that the Court schedule this matter for briefing and argument in tandem with *Medtronic, Inc.* v. *Lohr*, Nos. 95-754 and 95-886.

Respectfully submitted,

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